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HEWLETT-PACKARD COMPANY
Intellectual Property Administration
P.O. Box 272400
Fort Collins, CO 80527-2400

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BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Application Number: 10/801,379
Filing Date: March 15, 2004
Appellant(s): FIGUEROA ET AL.

Walter W. Karnstein
For Appellant

EXAMINER'S ANSWER

This is in response to the appeal brief filed April 10, 2007 appealing from the Office action mailed 12/19/2007.

(1) Real Party in Interest

A statement identifying by name the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

The examiner is not aware of any related appeals, interferences, or judicial proceedings which will directly affect or be directly affected by or have a bearing on the Board's decision in the pending appeal.

(3) Status of Claims

The statement of the status of claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1-7 and 25-29, not 1-7 and 27-29.

(The examiner assumes that "27-29" is a typographical error.)

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct.

(5) Summary of Claimed Subject Matter

The summary of claimed subject matter contained in the brief is correct.

(6) Grounds of Rejection to be Reviewed on Appeal

The appellant's statement of the grounds of rejection to be reviewed on appeal is substantially correct. The changes are as follows:

WITHDRAWN REJECTIONS

The following grounds of rejection are not presented for review on appeal because they have been withdrawn by the examiner. The examiner had previously rejected claims 1-2, 4-7 and 25-29 under 35 USC 102(b) as anticipated by or, in the alternative, under 35 USC 103(a) as obvious over Voss et al (4,322,449).

The examiner is withdrawing the 102(b) portion of the rejection.

Thus, the rejection of Claims 1-2, 4-7 and 25-29 under 35 U.S.C. 102(b) as anticipated by Voss et al. (4,322,449) is withdrawn.

(7) Claims Appendix

The copy of the appealed claims contained in the Appendix to the brief is correct.

(8) Evidence Relied Upon

4,322,499	Voss et al	3-1982
5,894,841	Voges	4-1999

(9) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

a) Claims 1-2, 4-7 and 25-29 are rejected under 35 U.S.C. 103(a) as obvious over Voss et al. (4,322,449).

Voss teaches a method of applying a bioactive agent to a delivery substrate in the form of dots forming a desired geometrical pattern (see Abstract; col. 5, lines 35-37). Voss teaches the control of various parameters, such as dots/second, volume/drop, number of ejection strokes, concentration of the bioactive, etc (1:60-65; 4:1-26; 6:1-7). As is known in the art and as taught in the specification, controlling the dot pattern, the size or shape of the dot, or the consistency of the size of the dots will inherently provide control over the dissolution rate. The precise nature of Voss' printing technique yields such control.

As for the limitation of first "identifying a target dissolution rate", Examiner notes that safe and effective administration of drug (bioactive agent) to a patient requires a precise does at an acceptable "target" dissolution rate. Medical professionals, such as doctors, pharmacists, and pharmaceutical company scientists, are of ordinary skill in this art. Medical personnel would have been aware that a too-rapid dissolution rate could lead to an over-dose, whereas a too-slow dissolution rate could lead to ineffective treatment levels. Neither of these risks is acceptable. Also, many medications are provided in a controlled release (CR) form to provide the correct dose over a period of time, inherently requiring the use of a target dissolution rate. Therefore, when creating a drug delivery substrate, it is Examiner's position that it would have been

obvious for one of ordinary skill in the art to identify, in addition to a desired target dose a target dissolution rate. The patterns of dots placed down on the delivery substrate of Voss would have been placed to achieve said target dissolution rate for the safety and health of patients.

One of ordinary skill in the art would have been well aware of the effects of surface area on dissolution rate, for example, that a plurality of small, thin dots would dissolve faster than a thick, large dot of the same total volume. As evidence of this awareness, as outlined above, Voss teaches control of the parameters that would have been known by ordinary artisans in the medical coating art at the time the invention was filed to impact dissolution rate. Voss also recognizes importance of dissolution rate in that the label on the carrier carries a "taking time", i.e., a reminder to the patient that the effectiveness of the bioactive is about to wear off, and a new dose needs to be administered. This requires a knowledge of the dissolution rate of the bioactive, among other parameters.

Voss' method produces less than 1% deviation from average (Ex. 3)

Voss teaches the use of a piezoelectric ejection element (see Abstract).

Voss provides the bioactive agent in a solvent (col. 5, lines 52-62), that inherently dries by evaporation, with precisely controlled concentration and drop volume (col. 6, line 5).

Regarding claim 25, a pattern will inherently impact the dissolution rate speed. In addition, Voss discloses irregularly shaped carriers (5:34-49), which shaping would inherently affect dissolution rate.

The active substance may be ground and suspended (5:50-55), thus controlling crystal morphology.

b) Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Voss, as applied above, in view of Voges (5,894,841).

Examiner maintains the rejection of the previous office action, which is re-stated herein: Voss teaches that which is disclosed above, namely forming droplets of bioactive agent using piezoelectric ejection elements. What Voss does not teach is the use of thermal ejection elements.

It is Examiner's position that these two species of inkjet printing are obvious variants that would have been known to an ordinary artisan and cites Voges for teaching the same.

Voges teaches a method of forming droplets of bioactive agent by using one of the two forms of inkjet printing, namely either a piezoelectric ejection device or a thermal ejection device.

Since Voss teaches printing precise drops of bioactive agent using a piezoelectric element, such as is used in inkjet printing, and Voges teaches that either the piezoelectric or thermal types of inkjet printing are suitable for forming precise droplets of bioactive agent, Voges would have reasonably suggested the use of a thermal element in the method of Voss. It would have been obvious to one of ordinary skill in the art to use the interchangeability teachings of Voges in the method of Voss to provide Voss with a suitable, successful alternative element for dosing dots in a precise manner.

(10) Response to Argument

a) The applicant has argued that Voss does not identify a target dissolution rate. The examiner disagrees in that the precise dosing of the active substance, with precise control over volume, spacing and concentration will have the effect of controlling the dissolution rate of the active substance, and these parameters are therefore selected with this control in mind. The fact that "taking time" is applied to the carrier is an indication that dissolution rate is being accounted for in the application of the bioactive to the carrier, even if the term "dissolution rate" is not explicitly stated.

In addition, an examiner may take into account the inferences and creative steps that a person of ordinary skill in the art would employ. Examiners may rely on their own technical expertise to describe the knowledge and skills of a person of ordinary skill in the art. Prior art is not limited just to the references being applied, but includes the understanding of one of ordinary skill in the art. The proper analysis is whether the claimed invention would have been obvious to one of ordinary skill in the art.

The applicant has also argued that Voss does not select a desired dot topography. The examiner would point to Voss's printing of dots in the form of letters (see Example 2) as one example of controlling dot topography.

The applicant has argued that Voss does not disclose textured versus smooth dot topography in affecting the dissolution rate. However, Voss discloses irregularly shaped carriers (5:34-49), which would be encompassed by surface topography, and which would inherently affect dissolution rate.

b) The applicant has argued that Voges provides no suggestion as to how to modify the dissolution rate of the droplets of its droplet dispenser.

The examiner's position if that Voges teaches a conventional alternative to the piezo dispenser of Voss, and is used for this teaching, not for a teaching of dissolution rate.

(11) Related Proceeding(s) Appendix

No decision rendered by a court or the Board is identified by the examiner in the Related Appeals and Interferences section of this examiner's answer.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

Erma Cameron

Conferees:

Erma Cameron

ERMA CAMERON
PRIMARY EXAMINER

Erma Cameron

/Jennifer Michener/

Quality Assurance Specialist, TC1700

Jennifer Michener

Tim Meeks

TIMOTHY MEEKS
SUPERVISORY PATENT EXAMINER